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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Stefan Vogelin

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EXAMINER

BOSWORTH, KAMI A

ART UNIT

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3767

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,463	Applicant(s) VOGELIN ET AL.	
	Examiner KAMI A. BOSWORTH	Art Unit 4177	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/25/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. This office action is responsive to the amendment filed on 7/10/2008. As directed by the amendment: claim 18 has been amended, claims 1-17 have been cancelled, and new claims 25-40 have been added. Thus, claims 18-40 are presently pending in this application.
2. Applicant's election of Group II in the reply filed on 7/10/2008 is acknowledged. Because applicant cancelled claims 1-17 of Group I, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The abstract of the disclosure is objected to because it exceeds 150 words in length. Correction is required. See MPEP § 608.01(b).

Claim Objections

5. Claim 18 is objected to because of the following informalities: The use of the term "the latter" in line 5 leads the claim to be unclear; it is suggested this term be replaced by the term "the valve seat". Appropriate correction is required.
6. Claim 19 is objected to because of the following informalities: The use of the term "the latter" in line 3 leads the claim to be unclear; it is suggested this term be replaced by the term "the breast shield connector". Appropriate correction is required.
7. Claim 22 is objected to because of the following informalities: The use of the term "the latter" in line 5 leads the claim to be unclear; it is suggested this term be replaced by the term "the valve seat". Appropriate correction is required.
8. Claim 31 is objected to because of the following informalities: The use of the term "the latter" in line 2 leads the claim to be unclear; it is suggested this term be replaced by the term "the foot". Appropriate correction is required.
9. Claim 33 is objected to because of the following informalities: The term "compact openings" lacks proper antecedent basis; it is suggested a phrase such as "a number of" or "a series of" precede the term "compact openings". Appropriate correction is required.
10. Claim 37 is objected to because of the following informalities: The term "peripheral openings" lacks proper antecedent basis; it is suggested the term "peripheral openings" be changed to the term "extending openings". Appropriate correction is required.

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11. Claim 40 is objected to because of the following informalities: The phrase "elastomer (TPE) in which the" should be removed so the claim reads "...valve body is made from a thermoplastic elastomer (TPE)". Appropriate correction is required.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 28 recites the limitation "compact openings" in line 1. There is insufficient antecedent basis for this limitation in the claims as it is unclear whether "compact openings" refer to the "openings" of claim 18 (line 6), the "elongate openings" of claim 18 (line 8), or a further set of openings not yet defined.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

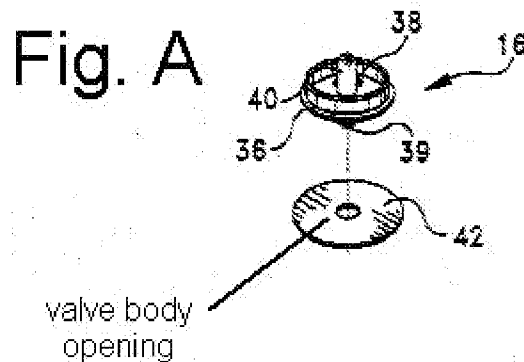
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 18, 19, 25, 26, 28, 30, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson (US Pat 5,415,632) in view of Guala (US Pat 6,390,130).

16. Re claim 18, Samson discloses a breast shield set 10 (Fig 1) for pumping off human breast milk, the breast shield set comprising a breast shield 24 (Fig 3), a breast

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shield connector 30 (Fig 3) with a threaded attachment (Col 3, Line 52) for connection to a milk collection vessel 14 (Fig 3), and a valve 16 (Fig 3) for limiting a dead volume during pumping off of breast milk, wherein the valve has a valve seat 36 (Fig 3) and a valve body 42 (Fig 3) with a circular diaphragm (Col 4, Lines 10-11), the valve body being arranged over the valve seat and closing the valve seat sealingly when it bears on said valve seat (Col 4, Lines 14-18), and the valve seat and valve body having openings (best shown in Fig A below) which are offset relative to one another (best shown in Fig A below) and which form a free passage when the diaphragm of the valve body lifts (Col 4, Lines 18-24). Samson does not disclose that the valve body openings are elongated, uniformly distributed along a circle, and are separated from one another by webs; nor does Samson teach that the diaphragm is designed to be weaker in the area adjacent to the webs.



Guala, however, teaches a diaphragm valve 9' (Fig 2) having elongate openings 14' (Fig 2) which are uniformly distributed along a circle in the periphery of the diaphragm (as seen in Fig 2) and wherein the elongate openings are separated from one another by webs 12' (Fig 2) for the purpose of being able to stop fluid flow when the valve is closed and to allow fluid flow when the valve is open. Therefore, it would have

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been obvious to one of ordinary skill in the art at the time of the invention to modify Samson to include a diaphragm valve having elongate openings separated by webs, as taught by Guala, for the purpose of stopping fluid flow when the valve is closed and allowing fluid flow when the valve is open.

Guala does not explicitly teach that the diaphragm is weaker in the area adjacent to these webs; however, the diaphragm will inherently be weaker in an area adjacent to the webs (in this instance, the area formed between sealing lip 13a (Fig 3) and peripheral section 10' (Fig 3)) than to another portion of the diaphragm (in this instance, the center of the central disk) since an area lying near an opening is inherently weaker than an area lying away from an opening.

17. Re claim 9, Samson discloses that the valve seat of the valve can be fitted onto the breast shield connector (Col 4, Lines 3-6).

18. Re claim 25, Samson discloses all the claimed features except that the circle has a center point that coincides with the center point of the circular diaphragm. Guala, however, teaches that the circle (formed by the elongated openings) has a center point that coincides with the center point of the circular diaphragm since the elongate openings are equally spaced from the center of central disk 11' (Fig 3; Col 4, Lines 33-38) for the purpose of ensuring a uniform shape and tight seal. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Samson to include coinciding center points, as taught by Guala, for the purpose of ensuring a uniform shape and tight seal.

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19. Re claim 26, Samson discloses all the claimed features except that the circular ring formed by the elongate openings has webs and a width that is a multiple smaller than the smaller radius of the circular ring. Guala, however, teaches that the elongate openings form a common circular ring (Fig 3; Col 4, Lines 33-38) provided with webs 12' (Fig 3) for the purpose of ensuring a uniform shape and tight seal. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Samson with a circular ring, as taught by Guala, for the purpose of ensuring a uniform shape and tight seal.

Further, Guala does not explicitly teach dimensions of the ring, however, it would have been obvious to one having ordinary skill in the art at the time the invention was made to create the circular ring formed by the elongate openings to have a width that is a multiple smaller than its smaller radius, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

20. Re claims 28 and 30, Samson discloses all the claimed features except that compact openings are present adjacent to the webs and are arranged in the weakened area of the diaphragm. Guala, however, teaches compact openings 14' (Fig 3) adjacent to webs 12' (Fig 3) that are arranged in the weakened area (the area formed between sealing lip 13a (Fig 3) and peripheral section 10' (Fig 3)) of the diaphragm for the purpose of regulating flow. Therefore, it would have been obvious to one of ordinary skill at the time of the invention to modify Samson to include compact openings arranged in a weakened area, as taught by Guala, for the purpose of regulating flow.

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21. Re claims 32 and 33, Samson discloses all the claimed features except that the valve body has a cylindrical jacket connected circumferentially to the plane disk diaphragm. Guala, however, teaches that the diaphragm except for the openings and weakened areas is designed as a plane, closed disk (Col 4, Line 34) which is connected circumferentially to a cylindrical jacket 10' (Fig 2) for the purpose of providing stability to the valve body. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Samson to include a cylindrical jacket, as taught by Guala, for the purpose of providing stability to the valve body.

22. Claims 22, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson in view of Edwards et al. (US Pat 5,025,829).

23. Re claim 22, Samson discloses a breast shield set 10 (Fig 1) for pumping off human breast milk, the breast shield set comprising a breast shield 24 (Fig 3), a breast shield connector 30 (Fig 3) with a threaded attachment (Col 3, Line 52) for connection to a milk collection vessel 14 (Fig 3), and a valve 16 (Fig 3) for limiting a dead volume during pumping off of the breast milk, in which the valve has a valve seat 36 (Fig 3) and a valve body 42 (Fig 3) closing the valve seat. Samson does not disclose that at least one part of the breast shield is made from a non-autoclavable material.

Edwards et al., however, teaches a valve body for use in pumping apparatuses that is made from thermoplastic elastomer (Col 2, lines 51-52), a known non-autoclavable material due to its poor heat resistance, for the purpose of providing adequate flexibility. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Samson to include a valve made of

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thermoplastic elastomer, as taught by Edwards et al., for the purpose of providing adequate flexibility.

24. Re claim 23, Samson discloses all the claimed features except that the valve body is made from the non-autoclavable material. Edwards et al., however, teaches a valve body 10 (Fig 1) for use in pumping apparatuses that is made from thermoplastic elastomer (Col 2, lines 51-52), a known non-autoclavable material due to its poor heat resistance, for the purpose of providing adequate flexibility. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Samson to include a valve made of thermoplastic elastomer, as taught by Edwards et al., for the purpose of providing adequate flexibility.

25. Re claim 24, Samson discloses that the breast shield and the breast shield connector are together formed in one piece (Fig 3; Col 3, Lines 50-53).

26. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson and Guala in view of Edwards et al. and Ytteborg (PG PUB 2003/0153869) .

27. Re claims 20 and 21, Samson and Guala disclose all the claimed features except that the breast shield, connector, and valve seat are made of the autoclavable material polypropylene and that the valve body is made of the non-autoclavable material thermoplastic elastomer. Ytteborg, however, teaches a breast shield set made entirely of the autoclavable material polypropylene (Para 58, Lines 1-7) for the purpose of allowing convenient cleaning. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Samson and Guala to include a

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breast shield, connector, and valve seat made of polypropylene for the purpose of allowing convenient cleaning.

Furthermore, Edwards et al. teaches a valve body 10 (Fig 1) for use in pumping apparatuses that is made from thermoplastic elastomer (Col 2, lines 51-52), a known non-autoclavable material due to its poor heat resistance, for the purpose of providing adequate flexibility. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Samson and Guala to include a valve body made of thermoplastic elastomer, as taught by Edwards et al., for the purpose of providing adequate flexibility.

28. Claims 27, 38, 39, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson and Guala in view of Edwards et al.

29. Re claim 27, Samson and Guala disclose all the claimed features except that exactly three elongate openings and three webs are present. Edwards et al., however, teaches a valve body 10 (Fig 1) having three elongate openings 16 (Fig 1) and three webs 20 (Fig 1) (Col 3, Lines 49-54) for the purpose of ensuring a uniform surface area. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Samson and Guala to include exactly three elongate openings and three webs for the purpose of ensuring a uniform surface area.

30. Re claims 38, 39, and 40, Samson and Guala disclose all the claimed features except that the valve body is made of the non-autoclavable material thermoplastic elastomer. Edwards et al., however, teaches a valve body 10 (Fig 1) for use in pumping apparatuses that is made from thermoplastic elastomer (Col 2, lines 51-52), a known

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non-autoclavable material due to its poor heat resistance, for the purpose of providing adequate flexibility. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Samson and Guala to include a valve body made of thermoplastic elastomer, as taught by Edwards et al., for the purpose of providing adequate flexibility.

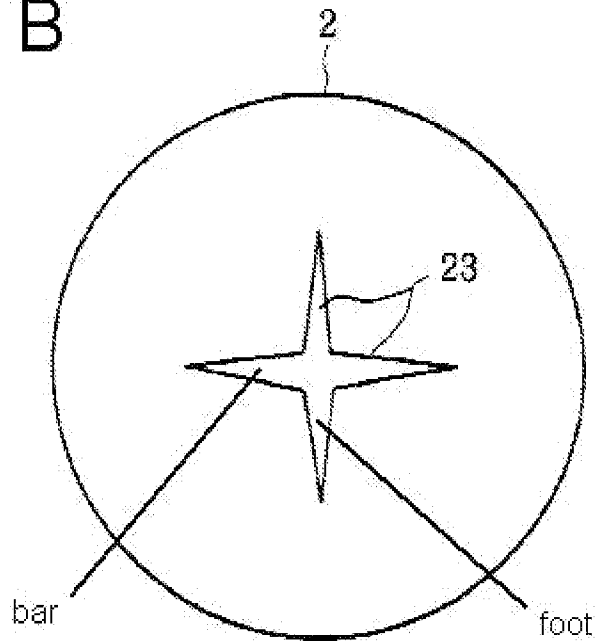
31. Claims 29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson and Guala in view of Okawa et al. (US Pat 5,897,033).

32. Re claims 29 and 31, Samson and Guala disclose all the claimed features except that the compact openings have a T-shaped configuration where a bar transversely extends over a foot oriented toward the webs and the center of the circle of the diaphragm. Okawa et al., however, teach a valve 2 (Fig 3b) having a compact opening 23 (Fig 3b) with a T-shaped configuration having a foot (best seen in Fig B below) and a bar (best seen in Fig C below) extending transversely over the latter for the purpose of regulating flow. Okawa et al. does not teach that the foot is oriented toward the webs and radially toward a center point of the circle of the diaphragm, however, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the shape and orientation of the compact openings of Guala to have a T-shaped configuration, as taught by Okawa et al., since such a modification would have involved a mere change in the form or shape of a component. A change in form or shape is generally recognized as being within the level of ordinary skill in the art. *In re Dailey*,

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149 USPQ 47 (CCPA 1976).

Fig. B



33. Claims 34, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson and Guala in view of Nuesch (US Pat 6,110,141).

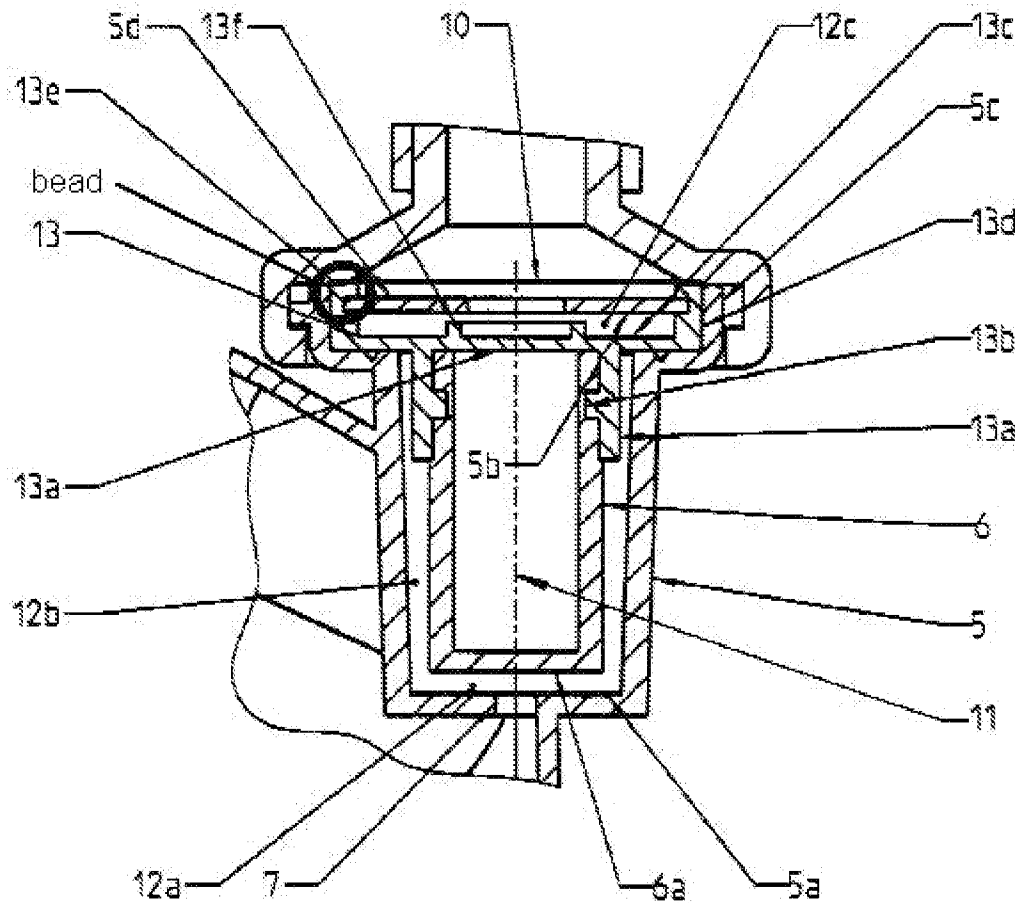
34. Re claims 34 and 35, Samson and Guala disclose all the claimed features except that the cylindrical jacket has at least one notch extending parallel to a center axis of the jacket and has an inner face provided with at least one groove extending at least partially about the circumference. Nuesch, however, teaches a cylindrical jacket 13d (Fig 3) having a notch (formed by groove 13e, Fig 2) extending parallel to a center axis 11 (Fig 2) and having an inner face (see in Fig 3) provided with one groove 13e (Fig 3) extending at least partially about the circumference for the purpose of holding other parts of the valve in a specific configuration. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Samson and Guala

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with a notch and a groove, as taught by Nuesch, for the purpose of holding other parts of the valve in a specific configuration.

35. Re claim 36, Samson and Guala disclose all the claimed features except that the cylindrical jacket is provided with a bead extending at least partially about the circumference. Nuesch, however, teaches a cylindrical jacket 13d (Fig 3) having a bead (formed above groove 13e as seen in Fig C below) extending about the circumference for the purpose of holding other parts of the valve in a specific configuration. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Samson and Guala with a bead, as taught by Nuesch, for the purpose of holding other parts of the valve in a specific configuration.

Fig. C



36. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Samson and Guala in view of Aoki et al. (US Pat 3,981,636).

37. Re claim 37, Samson and Guala disclose all the claimed features except that the valve seat has a plane surface with a central opening and extending openings interrupted by webs. Aoki et al., however, teaches a valve seat 62 (Fig 6) having a plane surface (as seen in Fig 5) with a central opening 621 (Fig 6) and with openings 622a (Fig 6) extending around this central opening, the extending openings being

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interrupted by webs (as seen in Fig 6) for the purpose of regulating flow. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Samson and Guala with a valve seat having extending openings and webs, as taught by Aoki et al., for the purpose of regulating flow.

Conclusion

38. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Niederberger (US Pat 6,042,560), Wilson (US Pat 5,358,476), Silver et al. (PG PUB 2004/0015127), and Hobbs (US Pat 4,813,932) disclose breast shield sets formed as one piece. Quay et al. (US Pat 6,287,521), Stuart (US Pat 4,680,028), and Beer et al. (US Pat 4,799,922) disclose breast shield sets made of autoclavable material. Szames et al. (US Pat 6,508,792), Leason et al. (US Pat 5,360,413), and Hunnicutt et al. (US Pat 6,764,286) discloses fluid delivery valves having valve bodies with openings and cylindrical jackets.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAMI A. BOSWORTH whose telephone number is (571)270-5414. The examiner can normally be reached on Monday - Thursday, 8:00 am to 4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Quang D. Thanh can be reached on (571)272-4982. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. A. B./
Examiner, Art Unit 4177

/Quang D. Thanh/
Supervisory Patent Examiner, Art
Unit 4177